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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,235	11/20/2006	Laura Serino	002441.00182	1557

27476 7590 12/16/2009

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EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,235	SERINO ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3 and 5-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicant's preliminary amendments filed 11/20/06 and 09/27/07.

Election

2) Acknowledgment is made of Applicants' election filed 09/28/09 in response to the written lack of unity and the species election requirement mailed 08/27/09. Applicants have elected invention I, claims 1-7. Applicants have further elected the gonococcal OmpA plus PPIase combination species via telephonic election on 11/19/08. See the interview summary dated 11/23/09. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

3) Claims 1-14 are pending.

Claims 3 and 5-14 are withdrawn from consideration as being directed to a non-elected invention or species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1, 2 and 4 are under examination. A First Action on the Merits has been issued on these claims.

Information Disclosure Statement

4) Acknowledgment is made of Applicant's Information Disclosure Statement filed 12/19/05. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' sequence listing which has been entered on 02/22/08.

Priority

6) The instant application is the national stage 371 application of PCT/IB2004/002421 filed

06/24/2004, which claims priority to application 0315021.6 filed 06/26/03 in the U.K.

Objection(s) to Specification

7) The specification is objected to for the following reason(s):

The use of trademark has been noted in this application. For example, see page 10 of the instant specification for 'Tween 80', 'Span 85', and 'pluronic' and see page 18 for 'Alexa Fluor'. Each trademark recitation must be capitalized. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicant examine the whole specification and make necessary changes wherever trademark recitations appear.

Rejection(s) under 35 U.S.C § 112, First Paragraph (Written Description)

8) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9) Claims 1, 2 and 4 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 2 and 4 depend from claim 1 and encompass a composition comprising a gonococcal OmpA protein comprising an amino acid sequence having 70% or more identity to SEQ ID NO: 2 and/or which is a fragment of at least 10 consecutive amino acids of SEQ ID NO: 2 and a gonococcal PPIase protein comprising an amino acid sequence having 70% or more identity to SEQ ID NO: 4 and/or which is a fragment of at least 10 consecutive amino acids of SEQ ID NO: 4. The objective of the instant invention is to use the instantly claimed composition for providing immunity against gonococcal disease and/or infection and for minimizing macrophage invasion by gonococcus. See paragraph bridging pages 1 and 2 of the instant specification. Thus, the instant application intends at least an anti-gonococcal prophylactic or vaccination application for the claimed composition.

The written description requirement can be met by describing the claimed subject matter to a person skilled in the art using sufficiently detailed, relevant identifying characteristics such as functional characteristics, and correlating those functional characteristics with a disclosed structure. See *Enzo Biochem v. Gen-Probe,* 323 F.3d 956, 964, 967, 968 (Fed. Cir. 2002). *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1980), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, 'not a mere wish or plan for obtaining the claimed chemical invention.' *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ('PTO') Guidelines for Examination of Patent Applications under the 35 U.S.C 112, 1 'Written Description' Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by 'showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, 'including, *inter alia*, 'functional characteristics when coupled with a known or disclosed correlation between function and structure ….', *Enzo Biochem, Inc. v. Gen-Probe*, 296 F.3d, 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *University of Rochester v. G.D. Searle & Co.*, 249 F, Supp.2d 216, 225 (W.D.N.Y. 2003).

The recited amino acid sequences having 70% or more identity to SEQ ID NO: 2 and SEQ ID NO: 4 represent a huge genus of gonococcal OmpA and PPIase antigens. A review of the instant specification indicates a lack of adequate description for a representative number of the gonococcal OmpA and PPIase antigen genera having 70% or more identity to SEQ ID NO: 2 and SEQ ID NO: 4 (i.e., variants) respectively and which are at least ten amino acid-long fragments thereof, having prophylactic functions. The structure, formula, physical properties, and the detailed relevant identifying characteristics of the two particular antigen genera from a representative number of gonococcal strains or isolates are not described, nor have their structure been correlated with the required functions, i.e., the ability to provide immunity against gonococcal disease and/or infection and to minimize macrophage invasion by homologous or heterologous gonococcus. The single species of the gonococcal OmpA amino acid sequence and

the single species of the gonococcal PPIase amino acid sequence that Applicants were in possession at the time of the invention were SEQ ID NO: 2 and SEQ ID NO: 4 respectively. See lines 14 and 15 of page 2 and lines 16 and 17 of page 3 of the specification. However, this description of the single gonococcal OmpA and PPIase protein species within the claimed genus may not be sufficient to support the patentability of the vast genus having the requisite function under 35 U.S.C § 112, first paragraph. See *University of California v. Eli Lilly & Co.*, 119 F.3d 15559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). The paragraph thereafter mentions of amino acid sequence variants, homologs, mutants etc. having 70% or more identity thereto and fragments thereof. Note that the amino acid sequences having 70% or more identity to SEQ ID NO: 2 or 4 would have up to 30% non-identity to SEQ ID NO: 2 or 4. However, the specification fails to describe the precise structure of such variants and/or fragments and correlate their structure with the requisite function, i.e., the ability to provide immunity against gonococcal disease and/or infection and to minimize macrophage invasion by homologous or heterologous gonococcus. Thus, a huge number of variant and derivative species of variable structure are encompassed within the scope of the claimed invention, but are not adequately described and a structure-function correlation established. Furthermore, Applicants were simply not in possession of a composition comprising a gonococcal OmpA protein comprising an amino acid sequence having 70% or more identity to SEQ ID NO: 2 **and** which is a fragment of at least 10 consecutive amino acids of SEQ ID NO: 2 and a gonococcal PPIase protein comprising an amino acid sequence having 70% or more identity to SEQ ID NO: 4 **and** which is a fragment of at least 10 consecutive amino acids of SEQ ID NO: 4, wherein the composition had prophylactic functions against homologous and/or heterologous gonococci. This is important because whether or not a composition comprising said gonococcal OmpA protein variants and PPIase variants having up to 30% sequence non-identity retain prophylactic functions against homologous and/or heterologous gonococci, is not predictable. The variations within the encompassed genus are huge. Although a microbial polypeptides having up to 30% non-identity with the native proteins are expected in the art to generally induce some antibodies, the binding specificity of such antibodies to the native polypeptides and therefore their ability to provide immunity against gonococcal disease and/or infection and to minimize macrophage invasion by homologous or heterologous gonococcus, is not predictable. The art reflects unpredictability as

to which amino acids in a specific protein or polypeptide can be varied, i.e., replaced or added, without adversely affecting the functional properties of that specific protein or polypeptide. In other words, the retention of the immunospecificity, cross-reactivity, and/or adherent ability following one or more amino acid substitutions within a bacterial polypeptide or within an epitope or fragment thereof, is not predictable. For instance, McGuinness *et al.* (*Mol. Microbiol.* 7: 505-514, Feb 1993) taught that "[a] single amino acid change within an epitope, or an amino acid deletion outside an epitope, were both associated with loss of subtype specificity resulting from a change in the predicted conformation at the apex of the loop structure" in case of a meningococcal polypeptide (see abstract). Similarly, McGuinness *et al.* (*Lancet* 337: 514-517, March 1991) taught that a point mutation generating a single amino acid change in a P1.16-specific epitope in the VR2 region of the *porA* gene of a strain of *Neisseria meningitidis* of subtype P1.7,16 resulted in "striking changes in the structural and immunological properties of the class 1 protein" of this isolate. See abstract and page 514 of McGuinness *et al.* Thus, these prior art references document the unpredictability in obtaining a functional variants of a microbial polypeptide or peptide that retains its specific immunological binding function(s). Applicants have not described what contiguous or discontiguous determinants, or conformational or non-conformational epitopes, or B-cell or T-cell epitopes of the claimed OmpA and PPIase variants are correlated with the required prophylactic function(s). The instant specification does not disclose which up to 30% of amino acid residues should be changed within the disclosed amino acid sequence species of SEQ ID NO: 2 or SEQ ID NO: 4 in order to maintain the required biological functions, i.e., the prophylactic functions against homologous and/or heterologous *Neisseria gonorrhoeae* in humans or non-humans. Note that *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111* states that Applicant "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, is for purposes of the 'written description' inquiry, whatever is now claimed." See page 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." See page 1116 of *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111*. Applicants should also note that *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111* makes clear that the written description provision of 35 U.S.C § 112, first paragraph, is severable from its enablement provision. See page 1115. Irrespective of the

simplicity or complexity of the isolation method, conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. With respect to the written description requirement, while 'examples explicitly covering the full scope of the claim language' typically will not be required, a sufficient number of representative species must be included 'to demonstrate that the patentee possesses the full scope of the [claimed] invention'. *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). In the instant case, Applicants' specification does not contain adequate written description sufficient to show they had possession of the full scope of their claimed invention at the time the application was filed. The instant specification mentions of gonococcal OmpA and PPIase variants having up to 70% or greater sequence identity to the amino acid sequence of SEQ ID NO: 2 and 4 respectively. See the paragraph following lines 14 and 15 of page 2 and lines 16 and 17 of page 3 of the specification. However, the specification does not establish a correlation between the prophylactic function(s) against gonococci and the precise structure within the OmpA and PPIase variants responsible for those functions. Applicants have not described which of SEQ ID NO: 2's or SEQ ID NO: 4's amino acids can be varied such that the protein variants thereof still maintain the above-identified functional capacities. Which epitopes within SEQ ID NO: 2 and SEQ ID NO: 4 are *Neisseria gonorrhoeae*-specific such that they can be of prophylactic significance in gonococcal diseases is not adequately described. This is critically important, because the state of the art, for example, indicates that SEQ ID NO: 4 contains several at least ten amino acid long epitopes that are not specific to gonococci, but are shared by sequences of non-gonococcal bacteria such as *Acinetobacter lowffii* and *Legionella pneumophila.* See sequence alignments (A) and (B) set forth below:

```
A)  T44823
probable macrophage infectivity potentiator [imported] - Acinetobacter lwoffii
(fragment)
C;Species: Acinetobacter lwoffii
C;Date: 21-Jan-2000 #sequence_revision 21-Jan-2000 #text_change 09-Jul-2004
C;Accession: T44823
R;Nakar, D.; Gutnick, D.L.
submitted to the EMBL Data Library, July 1999
A;Description: Genomic organization of the wce region of Acinetobacter lwoffii RAG-1
required for emulsan biosynthesis.
A;Reference number: Z22856
```

```
A;Accession: T44823
A;Status: preliminary; translated from GB/EMBL/DDBJ
A;Molecule type: DNA
A;Residues: 1-178 <NAK>
A;Cross-references: UNIPROT:Q9RME0; UNIPARC:UPI00000BDD85; EMBL:AJ243431;
PIDN:CAB57192.1
A;Experimental source: strain RAG-1
C;Genetics:
A;Gene: mip
  Query Match              4.8%;  Score 13;  DB 2;  Length 178;
  Best Local Similarity   100.0%;
  Matches   13;  Conservative  0;  Mismatches  0;  Indels  0;  Gaps   0.
Qy        143 GVKTTASGLQYKI 155
              |||||||||||||
Db        125 GVKTTASGLQYKI 137

(B) S22665
mip protein - Legionella pneumophila
C;Species: Legionella pneumophila
C;Date: 19-Mar-1997 #sequence_revision 19-Mar-1997 #text_change 09-Jul-2004
C;Accession: S22665; A30591
R;Fischer, G.; Bang, H.; Ludwig, B.; Mann, K.; Hacker, J.
Mol. Microbiol. 6, 1375-1383, 1992
A;Title: Mip protein of Legionella pneumophila exhibits peptidyl-prolyl-cis/trans
isomerase (PPlase) activity.
A;Reference number: S22665; MUID:92349965; PMID:1379319
A;Accession: S22665
A;Status: preliminary
A;Molecule type: DNA
A;Residues: 1-233 <FIS>
A;Cross-references: UNIPROT:Q933L8; UNIPARC:UPI0000001582; GB:S42595; NID:g252462;
PIDN:AAB22717.1; PID:g252463
R;Engleberg, N.C.; Carter, C.; Weber, D.R.; Cianciotto, N.P.; Eisenstein, B.I.
Infect. Immun. 57, 1263-1270, 1989
A;Title: DNA sequence of mip, a Legionella pneumophila gene associated with macrophage
infectivity.
A;Reference number: A30591; MUID:89173328; PMID:2925252
A;Accession: A30591
A;Status: preliminary; not compared with conceptual translation
A;Molecule type: DNA
A;Residues: 1-134,'A',136-233
A;Cross-references: UNIPARC:UPI00000010BA
C;Superfamily: Escherichia colipeptidylprolyl isomerase fklB; BKBP-type peptidylprolyl
isomerase homology
C;Keywords: membrane protein
F;144-189/Domain: BKBP-type peptidylprolyl isomerase homology <PPI>
Query Match    4.0%;  Score 11;  DB 2;  Length 233; Best Local Similarity  100.0%;
Matches   11;  Conservative   0;  Mismatches   0;  Indels   0;  Gaps   0.

Qy        176 GRLIDGTVFDS 186
              ||||||||||| 
Db        153 GRLIDGTVFDS 163
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Clearly, Applicants did not describe the invention of the instant claims adequately to show that they had possession of the claimed genus of gonococcal antigen variants. See e.g., *Noelle v. Lederman*, 355 F.3d 1343, 1348, 69 USPQ2d 1508, 1513 (Fed. Cir. 2004) ('invention is, for

purposes of the written description inquiry, *whatever is now claimed*'). Applicants should note that written description requires more than a mere statement that something is a part of the invention and a reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Without a precise structure, and without a correlation between the structure and the function(s), the claims do little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. Appl. & Int. 2007) citing *Eli Lilly*, 119 F.3d at 1568, 43 USPQ at 1406 ('definition by function ..... does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is'. Therefore, the claims are viewed as not meeting the written description provision of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

10) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

11) Claims 1, 2 and 4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1, 2 and 4 are indefinite in the use of the abbreviation 'PPIase' and/or 'OmpA' in the claim language. It is suggested that Applicants recite the full terminologies in the base claim while retaining the abbreviations within parentheses.

(b) Claim 2 is indefinite and confusing in the limitation: 'protein comprises an amino acid sequence … having 70% or more identity to SEQ ID NO: 2; **and** … which is a fragment of at least 10 consecutive amino acids of SEQ ID NO: 2' [Emphasis added]. The lower limit of 'at least 10 consecutive amino acids of SEQ ID NO: 2' is ten consecutive amino acids of SEQ ID NO: 2. It is unclear how a ten amino acid-long fragment of SEQ ID NO: 2 can have 70% or more identity to SEQ ID NO: 2, which is 225 amino acids in length.

(c) Analogous rejection and criticism apply to claim 4.

(d) Claims 2 and 4 are indefinite because these claims have improper antecedent basis in the limitation: 'the .... protein'. Claims 2 and 4 depend from claim 1, which does not include any limitation of a 'protein'.

(e) Claims 2 and 4, which depend from claim 1, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

12) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claims 1, 2 and 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Carson *et al.* (*J. Bacteriol.* 181: 2895-2901, 1999).

It is noted that the gonococcal antigens recited in the instant claims are not required to be isolated and/or purified, and therefore read on the antigens as present on whole cells of gonococci. It is further noted that the transitional recitation in the claims 'comprising' is open-ended claim language and therefore does not exclude additional, unrecited elements. See MPEP 2111.03 [R-1]. See *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts').

Carson *et al.* taught a composition comprising a whole cell lysate of FA1090 strain of *Neisseria gonorrhoaeae*. Carson *et al.* further taught a composition comprising proteins separated from said whole cell lysate. See first full paragraph under 'Materials and Methods' and first full paragraph on page 2897; and Table 1. The strain of *Neisseria gonorrhoaeae* from which the prior art proteins were obtained was the FA1090 strain, the same strain used in the instant specification. Therefore, the prior art composition necessarily comprises the same OmpA

having the amino acid sequence of SEQ ID NO: 2 and the same PPIase having the amino acid sequence of SEQ ID NO: 4 as that of the instantly claimed composition.

Claims 1, 2 and 4 are anticipated by Carson *et al.*

14) Claims 1, 2 and 4 are rejected under 35 U.S.C § 102(a) as being anticipated by Fontana *et al.* (WO 02/079243 A – Applicants' IDS).

Fontana *et al.* taught a composition comprising gonococcal antigens, immunogens, proteins or polypeptides such as the instantly recited OmpA amino acid sequence of SEQ ID NO: 2 and the PPIase amino acid sequence of SEQ ID NO: 4. See abstract; lines 16-32 and 37 of page 1; lines 22-26 of page 2; lines 1-30 of page 18; lines 1-7 of page 19; claims 11-14; SEQ ID NO: 26 on page 175; examples 13, 41, 117 and 160; and the sequence alignments below.

```
ABP77252
ID   ABP77252 standard; protein; 334 AA.
AC   ABP77252;
DT   07-MAR-2003  (first entry)
DE   N. gonorrhoeae amino acid sequence SEQ ID 1034.
KW   Antibacterial; infection; vaccine; gene therapy.
OS   Neisseria gonorrhoeae.
PN   WO200279243-A2.
PD   10-OCT-2002.
PF   12-FEB-2002; 2002WO-IB002069.
PR   12-FEB-2001; 2001GB-00003424.
PA   (CHIR ) CHIRON SPA.
PI   Fontana MR,  Pizza M,  Masignani V,  Monaci E;
DR   WPI; 2003-058415/05.
DR   N-PSDB; ABZ38222.
PT   New protein from Neisseria gonorrheae, useful for the manufacture of a
PT   medicament for treating or preventing N. gonorrheae infection.
PS   Disclosure; Page 263; 815pp; English.
CC   The present invention relates to proteins from Neisseria gonorrhoeae.
CC   Also disclosed are the nucleic acid molecules encoding the proteins and
CC   antibodies that specifically bind to the proteins. The composition
CC   comprising the protein, nucleic acid or antibody is useful for the
CC   manufacture of a medicament for treating or preventing N. gonorrhoeae
CC   infection, this may be in the form of a vaccine or gene therapy.
CC   Sequences given in records ABP76736-ABP81046 represent nucleic acid
CC   molecules of the invention
SQ   Sequence 334 AA;

Query Match 100.0%;  Score 272; DB 1; Length 334; Best Local Similarity  100.0%
Matches  272;  Conservative   0;  Mismatches   0;  Indels   0;  Gaps  0.

Qy          1 MNTIFKISALTLSAALALSACGKKEAAPASASEPAAASAAQGDTSSIGSTMQQASYAMGV 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         63 MNTIFKISALTLSAALALSACGKKEAAPASASEPAAASAAQGDTSSIGSTMQQASYAMGV 122

Qy         61 DIGRSLKQMKEQGAEIDLKVFTDAMQAVYDGKEIKMTEEQAQEVMMKFLQEQQAKAVEKH 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        123 DIGRSLKQMKEQGAEIDLKVFTDAMQAVYDGKEIKMTEEQAQEVMMKFLQEQQAKAVEKH 182
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```
Qy        121 KADAKANKEKGEAFLKENAAKDGVKTTASGLQYKITKQGEGKQPTKDDIVTVEYEGRLID 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        183 KADAKANKEKGEAFLKENAAKDGVKTTASGLQYKITKQGEGKQPTKDDIVTVEYEGRLID 242

Qy        181 GTVFDSSKANGGPATFPLSQVIPGWTEGVRLLKEGGEATFYIPSNLAYREQGAGEKIGPN 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        243 GTVFDSSKANGGPATFPLSQVIPGWTEGVRLLKEGGEATFYIPSNLAYREQGAGEKIGPN 302

Qy        241 ATLVFDVKLVKIGAPENAPAKQPDQVDIKKVN 272
              ||||||||||||||||||||||||||||||||
Db        303 ATLVFDVKLVKIGAPENAPAKQPDQVDIKKVN 334
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ABP76748

```
ID   ABP76748 standard; protein; 225 AA.
AC   ABP76748;
DT   15-JUN-2007  (revised)
DT   07-MAR-2003  (first entry)
DE   N. gonorrhoeae amino acid sequence SEQ ID 26.
KW   Antibacterial; infection; vaccine; gene therapy; BOND_PC;
KW   hypothetical protein;
KW   hypothetical protein NGO1559 [Neisseria gonorrhoeae FA 1090];
KW   conserved hypothetical protein;
KW   conserved hypothetical protein [Neisseria gonorrhoeae FA 1090].
OS   Neisseria gonorrhoeae.
PN   WO200279243-A2.
PD   10-OCT-2002.
PF   12-FEB-2002; 2002WO-IB002069.
PR   12-FEB-2001; 2001GB-00003424.
PA   (CHIR ) CHIRON SPA.
PI   Fontana MR,  Pizza M,  Masignani V,  Monaci E;
DR   WPI; 2003-058415/05.
DR   N-PSDB; ABZ37718.
DR   PC:NCBI; gi59718787.
PT   New protein from Neisseria gonorrhoeae, useful for the manufacture of a
PT   medicament for treating or preventing N. gonorrheae infection.
PS   Claim 1; Page 175; 815pp; English.
CC   The present invention relates to proteins from Neisseria gonorrhoeae.
CC   Also disclosed are the nucleic acid molecules encoding the proteins and
CC   antibodies that specifically bind to the proteins. The composition
CC   comprising the protein, nucleic acid or antibody is useful for the
CC   manufacture of a medicament for treating or preventing N. gonorrhoeae
CC   infection, this may be in the form of a vaccine or gene therapy.
CC   Sequences given in records ABP76736-ABP81046 represent nucleic acid
CC   molecules of the invention
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
SQ   Sequence 225 AA;
  Query Match             100.0%;  Score 225;  DB 1;  Length 225;
  Best Local Similarity   100.0%;  Pred. No. 3.1e-200;
  Matches  225;  Conservative  0;  Mismatches  0;  Indels  0;  Gaps   0.

Qy          1 MTFFKPSTVVLTASALALSGCVADPVTGQQSPNKSAMYGLGGAAVCGIVGALTHSGKGAR 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MTFFKPSTVVLTASALALSGCVADPVTGQQSPNKSAMYGLGGAAVCGIVGALTHSGKGAR 60

Qy         61 NSALACGAIGAGVGGYMDYQEQRLRQNLAGTQIEIQRQGNQIRLVMPESVTFATGSAALG 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 NSALACGAIGAGVGGYMDYQEQRLRQNLAGTQIEIQRQGNQIRLVMPESVTFATGSAALG 120

Qy        121 GSAQYALNTAAQTLVQYPDTTLTINGHTDNTGSDAVNNPLSQHRAQAVAYYLQTRGVAAS 180
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                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 GSAQYALNTAAQTLVQYPDTTLTINGHTDNTGSDAVNNPLSQHRAQAVAYYLQTRGVAAS 180

Qy        181 RLTVYGYGSHMPVASNATVEGRAQNRRVEILINPDQRAVNAARHM 225
                ||||||||||||||||||||||||||||||||||||||||||||
Db        181 RLTVYGYGSHMPVASNATVEGRAQNRRVEILINPDQRAVNAARHM 225
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Claims 1, 2 and 4 are anticipated by Fontana *et al.*

Remarks

15) Claims 1, 2 and 4 stand rejected.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

17) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

December, 2009